

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: GENERIC PHARMACEUTICALS  
PRICING ANTITRUST LITIGATION**

**MDL 2724  
16-MD-2724**

**THIS DOCUMENT RELATES TO:**

**HON. CYNTHIA M. RUFÉ**

***ALL ACTIONS***

**PRETRIAL ORDER NO. 160  
(STIPULATED HIPAA QUALIFIED PROTECTIVE ORDER)**

**AND NOW**, this 18th day of February 2021, the parties having stipulated to the terms set forth below to expedite the flow of discovery material, adequately protect confidential material, facilitate electronic discovery efforts, and ensure that protection is afforded to material so entitled in all cases in this Multi-District Litigation (the “MDL”), the Court hereby enters this Order.

**1. DEFINITIONS**

1.1 Protected Health Information (PHI): shall have the same scope and definition as set forth in 45 C.F.R. § 160.103, and includes, but is not limited to, health information, including demographic information, relating to either: (a) the past, present, or future physical or mental condition of an individual, (b) the provision of health care to an individual, or (c) the payment for the provision of health care to an individual, which identifies the individual or which reasonably could be expected to identify the individual.

1.2 Covered Entities: shall have the same scope and definition as set forth in 45 C.F.R. § 160.103.

1.3 De-Identified Information: shall have the same scope and definition as set forth in 45 C.F.R. § 164.514(a).

1.4 Individual: shall have the same scope and definition as set forth in 45 C.F.R. § 160.103.

1.5 Party: shall have the same scope and definition as set forth in Pretrial Order 53 (Protective Order).

1.6 Unstructured Data: shall have the same scope and definition as set forth in Pretrial Order No. 95 (ESI Protocol).

1.7 Search Term: shall have the same scope and definition as set forth in Pretrial Order No. 95 (ESI Protocol).

## **2. SCOPE**

2.1 This Order shall apply to all discovery material sought or produced from Unstructured Data sources through the use of Search Terms designed to capture potentially relevant information.

2.2 This Order does not entitle any Party to documents or information to which they would not otherwise be entitled under the Federal Rules of Civil Procedure, applicable discovery rules, and other pretrial orders. Nothing in this Order shall preclude either Party from asserting any objection to the relevance, discoverability, admissibility, or privileged nature of the documents containing PHI authorized to be disclosed by this Order.

2.3 The Parties may seek additional protection from the disclosure and use of any documents and information for which they believe this Order does not provide adequate protection or with respect to documents and information that they believe are not subject to disclosure pursuant to applicable statutes, rules, regulations or other applicable law.

2.4 This Order does not control or limit the use of PHI that was received by means other than through this Order (for example, through consent of the individual or through a public records request).

### **3. PRODUCTION AND USE OF PROTECTED HEALTH INFORMATION**

3.1 In accordance with the requirements of the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), specifically, 45 C.F.R. § 164.512(e)(1)(ii)(B) and § 164.512(e)(1)(v), the Court hereby enters this HIPAA Qualified Protective Order, as that term is defined in the foregoing regulations. In addition to the foregoing federal laws and regulations, this Order is entered to facilitate compliance with applicable state laws and regulations governing patient privacy and protecting healthcare information.

3.2 All Covered Entities who receive or have already received in this MDL a discovery request for Unstructured Data in the form of Search Terms are hereby authorized to disclose PHI to the extent necessary to comply with such a discovery request. Covered Entities may disclose PHI pursuant to this Order to any Party in the MDL or to any Party's attorney (including the agents and employees of the Parties and their attorneys) without violating the provisions of HIPAA. A Party producing documents of Covered Entities that contain PHI shall first stamp each document containing PHI with the following stamp: "Protected Health Information Subject to HIPAA Qualified Protective Order."

3.3 All Parties and their attorneys (including the agents and employees of the Parties and their attorneys) are hereby authorized through discovery in this case to disclose, receive, subpoena, and transmit PHI in Unstructured Data. The Parties may not object to Search Terms designed to capture potentially relevant Unstructured Data on the basis that the documents or information sought contain PHI protected by HIPAA.

3.4 Before disclosure of any PHI is made under this Order, the person to whom disclosure is to be made shall execute a copy of the attached Acknowledgement and Agreement to be Bound by Qualified Protective Order (“Acknowledgment”), attached hereto as Exhibit A; however, this requirement does not apply for disclosures to:

- a. any officer, director, or employee of a Party who is required in good faith to provide material assistance in the conduct of this MDL;
- b. Parties’ In House Counsel, as defined in paragraph 1.14 of Pretrial Order No. 53;
- c. Outside Counsel for the Parties, as defined in paragraph 1.13 of Pretrial Order No. 53;
- d. this Court, or any other court exercising jurisdiction with respect to this MDL, any appellate court(s), court personnel, and qualified persons (including necessary clerical personnel) recording, taking or transcribing testimony or argument at any deposition, hearing, trial or appeal in this MDL;
- e. any other person designated by the Court upon such terms as the Court may deem proper;
- f. any Special Master engaged by the Parties or authorized by the Court for purposes of dispute resolution regarding issues arising in this MDL; or
- g. a witness at a deposition, who may state on the record under oath that he or she agrees to be bound by this Order to the same extent as provided for in Exhibit A.

3.5 Pursuant to 45 C.F.R. § 164.512(e)(1)(v)(A), the Parties and their attorneys shall be allowed to use or disclose PHI for this litigation, and any appeals, settlement, enforcement, or monitoring that may result. The Parties and their attorneys may not use the PHI for any other

purpose. Authorized uses include disclosure to the Court and support staff, Special Masters and their support staff, the Parties and the Parties' employees, their attorneys of record, the attorneys' firms (i.e., attorneys and support staff), the Parties' experts, consultants, mediators, court reporters, videographers, copy services, and e-discovery vendors.

3.6 If a Party wishes to file a document containing PHI with the Court, it must be filed under seal, following the appropriate procedures to do so in the applicable court. However, any Party may publicly file a pleading or document with the Court that describes, summarizes, or quotes PHI, as long as that Party redacts the name and date of birth of the Individual to whom the PHI pertains and complies with the de-identification requirements of 45 C.F.R. § 164.514, and simultaneously files an un-redacted version under seal, and provides a copy of the un-redacted version to the other Parties. Similarly, any Party may publicly file a document containing De-identified Information relating to an Individual (such as a medical record), as long as that Party redacts the name and date of birth of the Individual to whom the information pertains and complies with the de-identification requirements of 45 C.F.R. § 164.514, and files an un-redacted version under seal, and provides a copy of the un-redacted version to the other Parties.

3.7 Any Party may discuss PHI covered by this Order at a deposition. The Party must request that this portion of the testimony be marked as "Protected Health Information Subject to HIPAA Qualified Protective Order" in the deposition transcript. Any Party must comply with the redaction and de-identification requirements of this Order, as referenced in the preceding paragraph, before filing a deposition or portion of a deposition containing PHI with the Court.

3.8 Any Party may use documents containing PHI at trial, an evidentiary or other motion hearing, including but not limited to, introducing them into evidence and asking a witness about their contents. If a Party moves a document containing PHI into evidence and wants it to

be a part of the record, the Court shall appropriately instruct the Clerk on how to handle such documents.

#### **4. DESTRUCTION OF PROTECTED HEALTH INFORMATION AND INADVERTENT DISCLOSURE**

4.1 Pursuant to 45 C.F.R. § 164.512(e)(1)(v)(B), within 60 days from the conclusion of these proceedings, any recipient of PHI under this Order shall either return the PHI to the Covered Entity that provided it or destroy the PHI (including all copies). For purposes of this Order, the conclusion of these proceedings shall mean the point at which this litigation is fully concluded, including by settlement or final order by the trial court ending the case; the conclusion of any appeals and proceedings on remand; the expiration of time for any Party to seek further appellate review; and/or whenever a period of enforcement, monitoring, or court retention of jurisdiction (whether determined by a settlement agreement or court order) terminates. The conclusion of these proceedings shall be the latest of any of the foregoing dates. Notwithstanding this provision, attorneys for the Parties are entitled to retain an archival copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert reports, attorney work product, and consultant and expert work product, even if such materials contain PHI. Any such archival copies that contain or constitute PHI remain subject to this Order.

4.2 If any Party learns that, by inadvertence or otherwise, PHI has been disclosed to or accessed by any person or in any circumstance not authorized under this Order, the Party must, not later than 10 calendar days after learning of the disclosure: (a) notify in writing relevant Parties, including the Covered Entity who supplied the PHI of the unauthorized disclosure or access; (b) if the Party is the one who made the unauthorized disclosure or access, use its best efforts to retrieve all PHI that was improperly disclosed or terminate the unauthorized

access; (c) inform the person or persons to whom unauthorized disclosures or access were made of all the terms of this Order; and (d) request that such person or persons execute the

Acknowledgment attached hereto.

It is so **ORDERED**.

**BY THE COURT:**

**/s/ Cynthia M. Rufe**

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**CYNTHIA M. RUFÉ, J.**

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**ACKNOWLEDGMENT AND AGREEMENT  
TO BE BOUND BY QUALIFIED PROTECTIVE ORDER**

I, \_\_\_\_\_ [print or type full name],  
\_\_\_\_\_ [print position  
of employment, firm name, and full address], declare under penalty of perjury that I have read in  
its entirety and understand the HIPAA Qualified Protective Order issued by the United States  
District Court for the Eastern District of Pennsylvania on February 18, 2021 (Pretrial Order No.  
160) in the action *In re: Generic Pharmaceuticals Pricing Antitrust Litigation*, MDL No. 2724  
(the “Order”).

I agree to comply with and to be bound by all the terms of the Order, including the  
Destruction of Protected Health Information and Inadvertent Disclosure procedures delineated in  
Section 4 of the Order. I promise that I will not disclose in any manner any information or item  
that is subject to the Order to any person or entity except in strict compliance with the provisions  
of the Order. I understand and acknowledge that failure to so comply could expose me to  
sanctions and punishment.

I further agree to submit to the jurisdiction of the United States District Court for the  
Eastern District of Pennsylvania for the purpose of enforcing the terms of the Order, even if such  
enforcement proceedings occur after termination of this MDL.

Dated: \_\_\_\_\_

City and State (or Country) where sworn and signed: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Signature: \_\_\_\_\_